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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,008	08/07/2006	Toshiharu Suzuki	3749-0112PUS1	7226

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EXAMINER

CHERNYSHEV, OLGA N

ART UNIT	PAPER NUMBER
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1649

NOTIFICATION DATE	DELIVERY MODE
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12/10/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No. 10/577,008	Applicant(s) SUZUKI ET AL.	
	Examiner Olga N. Chernyshev	Art Unit 1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6 and 10-16 is/are pending in the application.
- 4a) Of the above claim(s) 14 and 15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6, 10-13 and 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Claims 1-4, 6 and 10-13 have been amended, claims 5 and 7-9 have been cancelled and claim 16 has been added as requested in the amendment filed on October 07, 2008.

Following the amendment, claims 1-4, 6 and 10-16 are pending in the instant application.

2. Claims 14-15 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on April 17, 2008.

3. Claims 1-4, 6, 10-13 and 16 are under examination in the instant office action.

4. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

5. Applicant's arguments filed on October 07, 2008 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Rejections - 35 USC § 112, including new grounds of rejection

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-4, 6, 10-13 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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8. Claims 1-4 and 6 stand vague and ambiguous for reasons of record in section 11 of Paper mailed on July 07, 2008. At pp. 8-9 of the Response, Applicant submits that the claims have been amended to obviate this ground of rejection. Applicant's argument has been fully considered but is not persuasive because the claims remain indefinite. Specifically, claim 1 encompasses peptides structurally defined as being related to the polypeptide of SEQ ID NO: 1 and "being obtained by cleaving an N-terminal region and a C-terminal region of" the polypeptide of SEQ ID NO: 1. The phrase "being obtained by" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. The similar limitation is present in claim 3, "region is cleaved by presenilin", which makes the claimed peptide vague and indefinite because it is not obvious how the phrase affects the structure of the peptide in any particular way. Further, as fully explained in the previous office action of record, the claims recite references to potential sites of cleaving "Alcadein α ", portions of the extracellular domains and enzymes that cleave Alcadein α , and such language absent an explicit reference to the molecular structure renders the claims vague and indefinite. Again, because the structure of the claimed products is not obvious from the claims, it is impossible to evaluate if the claimed subject matter reads on specific peptides or encompasses a genus of products and, therefore, if it meets the requirements of 35 U.S.C. 112, first paragraph, written description. The proper dependency of the claims 2-4 and 6 cannot be assessed as well.

9. Claims 12, 13 recite the limitations "ratio" and "high-molecular-weight peptide" in claim 10. There is insufficient antecedent basis for these limitations in the claims.

10. Claim 13 is vague and ambiguous for recitation of points of cleavage of the peptide that are "closer", terms "change" and observing the "change", which are all relative

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terms presented without giving a point of reference to ascertain the required degree.

Furthermore, claim 13, as currently amended, is missing a critical step, which is the step that identifies a therapeutic agent for AD.

11. Claims 10 and 16 are indefinite for being dependent from indefinite claims.

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claims 10-13 and 16 are rejected under 35 U.S.C. 112, first paragraph, for reasons of record as applied to claims 7-13 in section 16 of Paper mailed on July 07, 2008. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

At p. 11 of the Response, Applicant submits that, "Applicants have cancelled claims 7-9, without prejudice or disclaimer, thus obviating the rejection as to these claims. Applicants respectfully traverse as to the remaining claims. Although Applicants disagree, in order to further prosecution, Applicants have amended claim 10-13, without prejudice or disclaimer, as described in the previous rejections, above." Applicant's statement has been fully considered, however, it failed to meet the requirements of 37 CFR 1.111 (b),

In order to be entitled to reconsideration or further examination, the applicant or patent owner must reply to the Office action. The reply by the applicant or patent owner must be reduced to a writing which distinctly and specifically points out the supposed errors in the examiner's action and must reply to every ground of objection and rejection

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in the prior Office action. The reply must present arguments pointing out the specific distinctions believed to render the claims, including any newly presented claims, patentable over any applied references. If the reply is with respect to an application, a request may be made that objections or requirements as to form not necessary to further consideration of the claims be held in abeyance until allowable subject matter is indicated. The applicant's or patent owner's reply must appear throughout to be a bona fide attempt to advance the application or the reexamination proceeding to final action. A general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references does not comply with the requirements of this section. (Emphasis added). MPEP 714.02.

In the instant case, Applicant did not presents any arguments to point out specific errors in Examiner's reasoning supporting the instant rejection, or explain as how the claims, as currently presented, obviate the instant lack of enablement rejection.

Applicant is advised that claims 10-13 and new claim 16, as currently presented, fail to satisfy the enablement requirement for reasons of record fully explained in the previous office action of record and, therefore the rejection is maintained.

Conclusion

14. No claim is allowed.

15. This application contains claims 14-15 drawn to an invention nonelected with traverse in Paper filed on April 17, 2008. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

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16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey J. Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Olga N. Chernyshev, Ph.D.
December 04, 2008

/Olga N. Chernyshev/
Primary Examiner, Art Unit 1649